

**REMARKS**

**Status of the Application and Claim Amendments**

Claims 24-42 are currently pending. The Office has withdrawn all but claims 24-35 and 41. Applicant respectfully notes that the Office Action Summary states that "claim(s) 24-35 and 41 is/are pending." However, Applicant has not cancelled claims 36-40 or 42. Those claims remain pending and instead are merely withdrawn from current examination, as the Office then recognizes at page 2 of the Office Action.

Applicant also kindly requests the Examiner to acknowledge the priority claims in the next Office paper. The present application is the National Stage of PCT Application No. PCT/EP2004/006515, filed June 17, 2004 and also claims priority to German Application No. 103 28 080.4, filed June 20, 2003. The Official Filing Receipt mailed June 8, 2006, acknowledges those priority claims. (See also the Preliminary Amendment of December 20, 2005.)

Applicant herein amends claims 24, 26, and 28 as shown above. Support for those amendments may be found in the application as a whole, *inter alia*, at page 10, lines 14-29, at page 11, lines 14-25, at page 11, lines 26-35, and at page 12, lines 8-34. (See also pages 13-14.) Moreover, claims 28 and 31 previously used different numbering schemes when referring to SEQ ID NO:12, as explained in more detail below. For clarity, Applicant has amended claim 31 to use the same numbering scheme as claim 28. The two different numbering schemes are explained at page 12, lines 8-19, of the application. SEQ ID NO:12 is the segment of the hepatitis B virus S antigen at amino acid positions 43 to 196. But SEQ ID NO:12, like all sequence listings provided in patent applications, numbers the HBVsAg amino acid 43, which is the first

amino acid in SEQ ID NO:12, as amino acid 1. Accordingly, position 96 of the HBVsAg sequence is position 54 of SEQ ID NO:12, and so on. Thus, positions 54, 61, 72-76, 78, 85, 87, and 94 of SEQ ID NO:12 correspond to positions 96, 103, 114-118, 120, 127, 129, and 136 of the HBV S antigen amino acid sequence. (See also the sequence listing and a depiction of the sequence at page 24 of the application text.) To avoid any confusion, claim 31 is amended to use the numbering on the actual sequence listing for SEQ ID NO:12, as already provided in claim 28.

Applicant also amends claims 31 and 33 to correct inadvertent typographical errors. In claim 31, the article "a" was used rather than the article "an" at the beginning of the claim, while in claim 33 "HBV" (Hepatitis B virus) was mis-spelled "H8V." Applicant also amends claim 41 to insert the language from claim 36, thus rendering the claim independent.

The present amendments do not introduce new matter. Hence, Applicant respectfully requests their entry.

#### **Claim Objections**

The Office objects to claims 29, 33, and 41 for containing reference to a non-elected invention or for typographical errors. (Office Action at pages 2-3.)

The Office objected to claim 33 because of a mis-spelled abbreviation "H8V." That error has been corrected and the objection is now moot.

The Office objected to claim 29 for allegedly containing reference to non-elected inventions. However, Applicants do not believe there is any need to amend claim 29 as each of SEQ ID NO:12 to SEQ ID NO:30 is already being examined by the Office within

the context of claim 28, for example. Accordingly, once claim 28 is deemed allowable, there should be no objection to claim 29.

The Office objected to claim 41 for the same reason as claim 29. Claim 41 had depended upon withdrawn claim 36. Applicants have now made claim 41 independent, rendering the objection moot.

**Claims 24-35 and 41 Are Definite Under 35 U.S.C. § 112, Second Paragraph**

The Office rejects claim 24, contending that the metes and bounds of the phrase "at least 78% identity" to SEQ ID NO:14 is not sufficiently clear. Applicant traverses that rejection.

According to claim 24 as amended, the claim recites a polypeptide comprising an amino acid sequence with at least 81% identity to SEQ ID NO:14. As percent identity is standard terminology in the biochemical arts, there is no need for the present Applicant to use different language. For example, the document cited by the Office below (WO01/40279 to Stuyver et al.) uses the same terminology in its claim 1 (page 53) when it refers to "a sequence with at least 90% . . . identity to the sequence defined in SEQ ID NO:1." Indeed, the Office itself made its own calculations of percent identity when analyzing the related art, demonstrating that the Office understands the metes and bounds of this term. (See the Office Action at pages 4-5.)

In any event, further guidance as to the meaning of a percent identity is provided throughout the application text, such as at pages 10-11. The application points out, for instance, that computer programs may be used to calculate a percent identity of a sequence to a reference sequence, such as the Genetics Computer Group "Bestfit" sequence analysis program. (Application at page 11, lines 1-12.) The application also

describes exemplary differences that may exist from the reference SEQ ID NO:14 in the inventive polypeptides. (*Id.* at page 11, lines 14-25.) For example, as there described, 0 to 9 amino acid substitutions, insertions, or deletions may exist in the section of the claimed polypeptide that aligns with SEQ ID NO:14, which corresponds to at least 81% identity.

Moreover, Applicant points out that the standard for definiteness according to 35 U.S.C. § 112, second paragraph, is one of reasonableness, not absolute precision. M.P.E.P. § 2173.02. That standard is based upon how one of ordinary skill in the art, who has read the specification in full and who is aware of the terminology used in the related scientific literature, would understand the claims. M.P.E.P. § 2173.02; *and see Phillips v. AWH*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*) (explaining that claims are interpreted in light of the specification as a whole). The M.P.E.P. also counsels examiners that claims that are otherwise clear to one of ordinary skill in the art within the context of the application as a whole should not be rejected merely because they might have been phrased differently. M.P.E.P. § 2173.02.

For all of the reasons above, claim 24 and its dependents are definite and Applicant requests the withdrawal of this rejection.

**Claims 24, 26, 28-29, 31, 33-35, and 41 Are Novel Under 35 U.S.C. § 102**

The Office also rejects claims 24, 26, 28-29, 31, 33-35, and 41 as allegedly anticipated by published PCT application WO01/40279 to Stuyver et al. ("Stuyver"). (Office Action at pages 3-5.)

First, the Office contends that Stuyver teaches a sequence with at least 78% identity to SEQ ID NO:14 in Stuyver's Figure 6 (the HBsAg sequences). That basis of

rejection is now moot, as Applicants have amended claim 24 to recite a polypeptide comprising an amino acid sequence with at least 81% identity to SEQ ID NO:14 and claim 26 to recite a polypeptide comprising an amino acid sequence with from 0 to 9 changes compared to SEQ ID NO:14. No such sequences are disclosed in Stuyver. Hence, Stuyver fails to meet all of the required elements of claims 24 and 26 and their dependents.

Second, the Office contends that Stuyver teaches sequences comprising at least 5 consecutive amino acids from SEQ ID NO:12, and comprising at least one of the amino acid positions 54, 61, 72, 73, 74, 75, 76, 78, 85, 87, and 94 of SEQ ID NO:12, as recited in claim 28. Applicants have now amended claim 28 to recite sequences comprising at least 5 consecutive amino acids from SEQ ID NO:12, and comprising at least one of the amino acid positions 54, 61, 72, 73, 74, 75, 76, 78, 87, and 94 of SEQ ID NO:12, or comprising at least 6 consecutive amino acids from SEQ ID NO:12, and comprising amino acid position 85. As explained at page 12, lines 8-19, positions 54, 61, 72, 73, 74, 75, 76, 78, 85, 87, and 94 of SEQ ID NO:12 correspond to positions 96, 103, 114 to 118, 120, 127, 129, and 136 of the S antigen of HBV. (See Figure 6 of Stuyver.) Stuyver does not anticipate any of the sequences recited in amended claim 28, and accordingly cannot anticipate any of the sequences recited in claim 29. (See fuller discussion of this point below in reference to claim 31.) Hence, Stuyver fails to meet all of the required elements of claim 28 and its dependents.

Stuyver also fails to meet all of the requirements of claim 31 and its dependents. Claim 31 currently recites:

An oligopeptide or polypeptide, comprising a length of at least 5 amino acids, and comprising at least one of the

amino acid positions 54, 61, 72, 73, 74, 75, 76, 78, 87, and 94 of SEQ ID NO:12, or comprising a length of at least 6 amino acids, and comprising position 85 of SEQ ID NO:12, wherein position 54 is alanine, position 61 is isoleucine, position 72 is alanine, position 73 is isoleucine, position 74 is asparagine, position 75 is asparagine, position 76 is arginine, position 78 is glutamine, position 85 is threonine, position 87 is histidine, and position 94 is tyrosine.

Positions 54, 61, 72-76, 78, 85, 87, and 94 of SEQ ID NO:12 correspond to positions 96, 103, 114-118, 120, 127, 129, and 136 of the HBV S antigen amino acid sequence. (Application at pages 12, lines 8-19; Figure 6 of Stuyver.) In Stuyver's sequences, position 54 is valine, not alanine; position 61 is methionine, not isoleucine; position 72 is threonine or serine, and not alanine; position 73 is threonine, not isoleucine; position 74 is threonine, not asparagine; position 75 is serine, not asparagine; position 76 is threonine or alanine, not arginine; position 78 is proline, not glutamine; position 87 is glutamine, and not histidine, and position 94 is serine, and not tyrosine. (See Figure 6 of Stuyver.) Because Stuyver's amino acids at each of those positions differ, Stuyver cannot anticipate any sequence stretch of SEQ ID NO:12 containing such amino acids. In Stuyver's sequence D, position 85 is threonine, as also recited in claim 31. However, Stuyver's sequences cannot anticipate a 6-amino acid sequence stretch of SEQ ID NO:12 that includes position 85. In particular, in Stuyver's Sequences A, B, and G, position 85 is proline and not threonine, as claimed. In Stuyver's Sequences E and F, position 85 is leucine rather than threonine, as claimed. In Stuyver's Sequence C, position 84, which would be included in a 6-amino acid stretch including position 85, is isoleucine, and not threonine as it is in SEQ ID NO:12. Finally, in Stuyver's Sequence D, while position 85 is threonine, position 81 is arginine instead of threonine as in SEQ ID NO:12 and position 87 is glutamine instead of histidine as in

SEQ ID NO:12. Because any 6-amino acid stretch that includes position 85 must include at least one of positions 81 and 87, Sequence D also distinguishes from claim 31.

For all of the reasons above, Stuyver cannot anticipate any of the pending claims and Applicants request the withdrawal of this rejection and the allowance of claims 24-35 and 41.

**All of Claims 24-35 and 41 Are In Condition For Allowance**

Finally, the Office notes that all of claims 25, 27, 30, and 32 are free of the art. (Office Action at page 5.) Given the amendments and remarks above, and the Office's acknowledgement, all of claims 24-35 and 41 are now in condition for allowance.

**Request for Rejoinder of Method Claim 42**

Based on the Restriction Requirement leading to the withdrawal of claims 36-40 and 42, Applicant has a right to rejoin to this application any method of manufacturing or method of use claims either dependent upon the elected claims 24-35 and 41 or containing all of the limitations of those claims. M.P.E.P. § 821.04. Accordingly, Applicant requests the rejoinder of method claim 42, which is a method of use claim multiply dependent upon claims 24, 26, 28, 29, or 31.

**Conclusion**

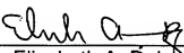
Thus, Applicant respectfully requests reconsideration and reexamination of this application and the immediate allowance of the elected claims and the rejoinder of claim 42. If the Examiner has any questions for Applicant, she is welcome to contact Applicant's representatives at her convenience.

Please grant any extensions of time required to enter this response and charge  
any required fees that are not attached to this Amendment to our deposit account  
06-0916.

Respectfully submitted,

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Dated: June 26, 2007

By:   
Elizabeth A. Doherty  
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**Attachments: Petition for Three-Month Extension of Time and fees  
Amendment Transmittal**